

Application No. 10/634,145  
Response Dated: March 13, 2008  
Docket No. NAA 0018 PA/41049.20

**Remarks:**

Claims 1 to 15 and 17 to 30 are pending.

**Rejection under 35 USC 101**

The Examiner rejected claims 1-15, 17-30 under 35 USC 101 as being drawn to non-statutory subject matter. In particular, the Examiner asserts that these claims lack a concrete, tangible and useful result, and indicated that this rejection can be overcome by reciting that a result of the process is outputted to a user. The applicant respectfully disagrees with this rejection. However, in order to advance prosecution, the independent claims have been amended as suggested by the Examiner.

Claims 1 and 21, as amended, each recite “providing said candidate model with optimized parameters to a user to be used for calculating said disease risk.” Claim 27, as amended, recites “providing said plurality of data sets and their associated weights to a user to be used for adjusting a statistical weight of each one of said data sets.” Claim 28, as amended, recites “providing said risk prediction model to a user to be used for predicting said disease risk.” Support for amended claims 1, 21 and 28 can be found at least at paragraphs [0011], [0029], [0039], [0090], and [0124]. Support for amended claim 27 can be found at least at paragraphs [0011], [0029], [0039], and [0083] to [0087].

It is believed that claims 1, 21, 27, and 28 each provide a concrete, tangible and useful result and are thus drawn to statutory subject matter. As the remaining pending claims are dependent from one or other of claims 1 and 28, they are also believed to provide such a result and being drawn to statutory subject matter.

Withdrawal of the rejection under 35 USC 101 is thus respectfully requested.

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Rejection under 35 USC 103

Claims 1, 2, 3, 9, 19, 20, 21, 23 and 28 to 30 are rejected under 35 USC 103(a) as obvious having regard to Dodds *et al.* (“Dodds”) in view of Luciano *et al.* (“Luciano”). Claims 1-15 and 17-30 are rejected under 35 USC 103(a) as obvious having regard to Dodds in view of Tibshirani and Nelson *et al.* (“Nelson”).

The Examiner stated that the arguments presented by the Applicant in the Response filed September 28, 2007 (“Previous Response”), are not persuasive. In particular, the Examiner characterized the Applicant’s arguments as asserting that “Dodds and Luciano fail to teach a statistical model for calculating disease risk as a function of non-genetic data.” This is a mischaracterization. One of the argument presented by the applicant was that the cited references fail to disclose or suggest a method in which the model itself uses non-genetic data as input but the parameters of the model are optimized using weights that are dependent on genetic data (see p. 15, 2<sup>nd</sup> paragraph of the Previous Response). None of the cited references, either alone or together, disclose or suggest optimizing the parameters of a risk prediction model by calculating weighted deviates using weights dependent on or reflecting genetic data, as recited in the respective claims of the present application, and as discussed in the Previous Response and further elaborated below.

The Examiner also alleged that previously presented claim 1 does not recite the feature that the parameters are optimized using weights which are dependent on the genetic data. The applicant respectfully disagrees.

Specifically, as indicated in the Previous Response (at page 14, last paragraph), claim 1 recites that the “weights associated with sets of said data having like genetic data are the same” (emphasis added). This means that the same weight is associated with data sets that have like genetic data, while the entire data collection is associated with different

weights. Thus, the recited weights are clearly dependent on genetic data. In any event, claim 1 and claim 21 have been each amended to clarify that “the weights used to weight said deviates are determined with a constraint that said weights associated with sets of said data having like genetic data are the same.”

It is also noted that independent Claim 28 recites the calculation of a sum of weighted deviates, where each deviate is predicted using a model and non-genetic data associated with a particular member, and the deviate is weighted by a “weight reflecting genetic data” associated with that member.

The current claims of the present application do not claim the concept of predicting disease risk using both genetic and non-genetic data in general, or using only non-genetic data. Rather, independent claims 1 and 28 are each directed to a specific method of using both types of data in a specific manner, as discussed above, so that “it is possible to untangle the interwoven and intractable relationship between them, and yet not ignoring the effects of either” (see paragraph [0095] of the present application). Each of the specific method as claimed is not disclosed or suggested in Todds taken either alone or in combination with any other cited reference(s).

Specifically, Todds is directed to the management of comprehensive and cumulative genetic and health assessment databases in relation to animals, in particular to bioinformatics system and its implementation in relation to animal biological data (col. 1, ll. 15 to 20 of Todds), and discloses a method, apparatus and system of obtaining, analyzing and reporting laboratory test data in relation to the heath assessment of an animal together with the genetic data related to that same animal (col. 4., ll. 39-42 of Todds). In particular, Todds discloses that “interpretation of PT [phenotype] and GT [genotype] 218 can be performed by an algorithm relating to the coefficients and predictability of information relating to disorders, disease and longevity when consider the data from the two databases

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PT 200 and GT 201. This can be done automatically [...] or there can be an expert interface 200 using skilled personnel to interpret the data of block 218" (see col. 21, ll. 44 to 57, and FIG. 6 of Todds). However, Todds does not disclose how the PT and GT data is interpreted at block 218. There is no recognition in Todds of the problems associated with interpreting both PT and GT data together, nor any solution for addressing these problems. In particular, there is no disclosure in Todds that a statistical predication model is or should be optimized by weighting deviates using weights that reflect genetic data, or that are determined with a constraint that the same weight is associated with data sets that have like genetic data.

The other cited references, including Luciano, also do not recognize and address these problems.

Therefore, it is submitted that current independent claims 1, 21, and 28, and their dependent claims, are allowable over the cited references, at least for the reasons given above, and for the reasons discussed in the Previous Response which are incorporated herein by reference.

The Examiner appears to assert that the features recited in claims 14 and 27 are disclosed by Tibshirani, and stated that the normalization factor "N" disclosed on page 386 line 2 of Tibshirani is considered as the "adjustment factor" recited in claims 14 and 27. The Applicant respectfully disagrees.

As recited in Claim 14 or claim 27, each data set is weighted by an adjustment factor or weight,  $a_i$ , which is calculated as:

$$a_i = \frac{n_i^p}{n_i^s},$$

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where  $n_i^p$  is the number of members in the population who share a same set of characteristics and  $n_i^s$  is the number of members associated with the collected data who share this set of characteristics. Thus,  $a_i$  is “indicative of the representativeness” of the particular member associated with the set of data. Each data set has its own adjustment factor/weight, and the values of the adjustment factor/weight will be different for different date sets when the characteristics of the corresponding members are different and have different popularities in the population.

In stark contrast, the number “N” in Tibshirani is a fixed number for a given data set, calculated as the sum of the square of all data values ( $x_{ij}$ ) (see page 386, line 2). The number N does not indicate the representativeness of any particular member associated with a given data set in the population. Tibshirani also does not otherwise disclose or suggest any adjustment factor or weight for individual data sets as claimed in claim 14 or 27 of the present application.

Thus, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 14 and 27, and claims 14 and 27 are allowable over the cited references.

Claims 1, 22, 27 and 28 are the only pending independent claims. The remaining claims are dependent claims and are thus also allowable, at least for being dependent directly or indirectly from an allowable independent claim.

In view of the foregoing, withdrawal of the rejections under 35 USC 103(a) is respectfully requested.

No new matter has been added by way of this amendment.

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In view of the foregoing, favourable consideration of the application is respectfully requested.

Respectfully submitted,

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